

**§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.**

(a) *Laboratory with a certificate of accreditation.* If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by HCFA, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in § 493.1806.

(b) *CLIA-exempt laboratory.* If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, HCFA directs the State to take appropriate enforcement action.

**§ 493.571 Disclosure of accreditation, State and HCFA validation inspection results.**

(a) *Accreditation organization inspection results.* HCFA may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) *State inspection results.* Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) *HCFA validation inspection results.* HCFA may disclose the results of all validation inspections conducted by HCFA or its agent.

**§ 493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.**

(a) *Comparability review.* In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, HCFA reviews the equivalency of requirements in the following cases:

(i) When HCFA promulgates new condition-level requirements.

(2) When HCFA identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by § 493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if HCFA determines an earlier review is required.

(b) *Validation review.* Following the end of a validation review period, HCFA evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) *Reapplication procedures.* (1) Every 6 years, or sooner, as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program must reapply for continued approval of a CLIA exemption. HCFA provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish HCFA, upon request, with the reapplication materials HCFA requests. HCFA establishes a deadline by which the materials must be submitted.

(d) *Notice.* (1) HCFA provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and HCFA is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of HCFA's review process on which the final determination is based and a description of the possible actions, as specified in § 493.575, that HCFA may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

**§ 493.575 Removal of deeming authority or CLIA exemption and final determination review.**

(a) *HCFA review.* HCFA conducts a review of the following:

(1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at § 493.573. HCFA reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at § 493.573. HCFA reviews, as appropriate, the criteria described in §§ 493.555 and 493.557(b) to reevaluate whether the licensure program continues to meet all these criteria.

(3) A review of an accreditation organization or State licensure program, at HCFA's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(4) A review of the accreditation organization or State licensure program

whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of HCFA or a HCFA agent for the following periods:

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

(b) *HCFA action after review.* Following the review, HCFA may take the following action:

(1) If HCFA determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, HCFA may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of HCFA's determination, or exempt status to a State within 30 days of HCFA's determination, both not to exceed 1 year, to afford the organization or State an opportunity to adopt equal or more stringent requirements.

(2) If HCFA determines that there are widespread or systematic problems in the organization's or State's inspection process, HCFA may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) *Final determination.* HCFA makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:

(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.

(2) Facility-specific data, as well as other related information.

(3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.

(4) The organization's accreditation requirements, or the State's licensure or approval requirements.